

TITLE 17. AIR RESOURCES BOARD

NOTICE OF PUBLIC HEARING TO CONSIDER AMENDMENTS TO THE ETHYLENE OXIDE AIRBORNE TOXIC CONTROL MEASURE FOR STERILIZERS AND AERATORS

The Air Resources Board (ARB or Board) will conduct a public hearing at the time and place stated below to consider the adoption of amendments to the Ethylene Oxide (EtO) Airborne Toxic Control Measure for Sterilizers and Aerators (ATCM). This regulation is being considered in an effort to simplify and clarify the ATCM to reflect implementation experience practices and, for large commercial ethylene oxide sterilizers, to integrate the State requirements with new federal requirements.

DATE: May 21, 1998

TIME: 9:30 a.m.

PLACE: Air Resources Board
Board Hearing Room, Lower Level
2020 L Street
Sacramento, California

This item will be considered at a two day meeting of the Board which will commence at 9:30 a.m., May 21, 1998. This item may not be considered until May 22, 1998. Please consult the agenda for the meeting, which will be available at least 10 days before May 21, 1998, to determine the day on which this item will be considered.

This facility is accessible to persons with disabilities. If accommodation is needed, please contact Ms. Lisa Williams at (916) 323-0440 or TDD (916) 324-9531 or (800) 700-8326 for TDD calls from outside the Sacramento area, by 14 days before May 21, 1998.

INFORMATIVE DIGEST OF PROPOSED ACTION/ PLAIN ENGLISH POLICY STATEMENT OVERVIEW

Proposed Actions and Sections Affected:

The Board staff is proposing to amend section 93108, Subchapter 7.5, Chapter 1, Part III, Title 17, California Code of Regulations -- Ethylene Oxide Airborne Toxic Control Measure for Sterilizers and Aerators. The proposed amendments include the following changes: creating section 93108.5 to separate the ATCM into two parts, one for non-commercial facilities and small commercial facilities, and the other for large commercial facilities; streamlining compliance testing requirements by allowing in some circumstances the calculation of control device efficiency using estimation techniques rather than measurement of EtO entering the control device; adding an alternative control efficiency requirement for a combined sterilizer and aerator exhaust stream; substituting a limit on ethylene oxide in liquid discharges for the current requirement that there be no discharge of sterilizer exhaust pump working fluid; and modifications to definitions to clarify

and improve the effectiveness of the ATCM. These proposed changes reflect criteria that were developed for control system testing during implementation of the ATCM, which was adopted by the Board in November 1990, and are consistent with the control requirements of the ATCM.

Ethylene oxide is a colorless, highly flammable and explosive gas used as a biocide to sterilize medical products and fumigate foodstuffs and other materials. After sterilization is complete and during aeration, the EtO is released. EtO was identified by the Board as a toxic air contaminant in November 1987. The Board subsequently adopted an ATCM for EtO from sterilizers and aerators. The ATCM requires that the EtO be controlled to performance standards which represent the lowest emissions achievable through the application of the best available control technology. There are several control technologies available that meet the performance standards; these include thermal incineration, catalytic oxidation, acid scrubbing (all of which destroy the EtO), and reclamation (which recovers the EtO for re-use).

The proposed changes include modifications to the compliance test method, ARB Method 431 (Title 17 CCR, section 94143). The changes to Method 431 are the inclusion of a method to calculate ethylene oxide at the control device inlet, a change in the length of time that ethylene oxide-containing air samples can be held before analysis from 24 hours to six hours, and inclusion of a test method for ethylene oxide in water.

Changes are proposed to the ATCM to simplify and incorporate into the ATCM the requirements of the federal National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations (NESHAP). A NESHAP is a federal regulation designed to reduce the emissions of hazardous air pollutants from facilities throughout the United States. On December 6, 1994, the United States Environmental Protection Agency (U.S. EPA) promulgated a NESHAP that affects six of the approximately 400 California facilities subject to the ATCM. The NESHAP imposes requirements for notification, emission control, and monitoring, recordkeeping, and reporting on ethylene oxide sterilizer and aerator facilities in California. Although these facilities are already in compliance with the more stringent emission control requirements of the ATCM, they must comply with additional notification, monitoring, recordkeeping, and reporting requirements of the NESHAP, whether or not the ATCM is amended. The proposed incorporation of the NESHAP requirements into the ATCM will, after approval of the ATCM by the U.S. EPA as equivalent to the NESHAP, simplify compliance for these commercial facilities. The NESHAP requirements proposed for inclusion in the ATCM are the following: addition of several definitions and modification of one existing definition for consistency with the NESHAP; addition of monitoring, recordkeeping, and reporting requirements; and, addition of a more stringent emission limit performance standard for aeration-only facilities. The emission limit performance standards of the existing ATCM, which are more stringent than the NESHAP requirements with the above-noted exception, are continued in the proposed amended ATCM.

Health and Safety Code sections 39658 and 39666 authorize the ARB to establish airborne toxic control measures for toxic air contaminants in accordance with specified criteria. Further, Health and Safety Code section 39659 provides that the ARB may adopt regulations which:

1) impose monitoring requirements, establish procedures for permits, and take any other action that may be necessary to establish, implement, and enforce programs for the regulation of hazardous air pollutants which have been listed as toxic air contaminants pursuant to subdivision (b) of section 39657, and 2) meet the requirements of subsection (l) of section 112 of the federal Clean Air Act (42 U.S.C. Secs. 7412(l)) and the guidelines and regulations adopted by the U.S. EPA pursuant to those sections. In adopting such regulations, the ARB is required to ensure that the requirements of the federal Act are met, and to use the definitions contained in subsection (a) of section 112 of the federal Act (42 U.S.C. Sec. 7412(a)).

Therefore, we propose to amend the ATCM to provide a single regulation that will continue to satisfy the existing State requirements and at the same time satisfy the federal requirements. The ARB staff held three public workshops, additional meetings with facility operators and representatives of the U. S. EPA, and numerous telephone conferences and conversations to solicit input from the public, the affected industries, and government agencies during the development of these amendments. In addition, staff visited over 30 facilities, tested emissions from 10 facilities, evaluated information from over 20 additional facilities, and mailed out approximately 800 notices and documents concerning the proposed amendments.

Availability Of Documents And Contact Person/ Plain English Policy Statement Overview

The Board staff has prepared a Staff Report which includes the initial statement of reasons for the proposed actions, including a summary of the environmental impacts of the proposal. Copies of the Staff Report and the full text of the proposed regulations are available and may be obtained from the Board's Public Information Office, 2020 L Street, Sacramento, California 95814, (916) 322-2990 at least 45 days prior to the scheduled hearing. The ARB has determined that it is not feasible to draft the regulation in plain English due to the technical nature of the regulation; however, a plain English summary of the regulation is available from the agency contact person named in this notice, and/or is also contained in the staff report for this regulatory action. Further inquiries regarding the proposed regulations should be directed to Mr. Ronald Walter, Stationary Source Division, Process Evaluation Section, at (916) 327-5974; 2020 L Street, Sacramento, California 95814.

Costs To Public Agencies And To Businesses And Persons Affected

In accordance with Government Code section 11346.5(a)(6), the Board's Executive Officer has determined that the regulations will create no cost in federal funding to the State, and will create a cost to a state agency, the ARB, which will be able to be absorbed within the ARB's existing budgets and resources. The Executive Officer has determined that the regulations impose no costs on local agencies that are required to be reimbursed under Part 7 (commencing with section 17500), Division 4, Title 2 of the Government Code. The regulations do not impose a mandate on local agencies that is required to be reimbursed pursuant to Section 6 of Article XIII B of the California Constitution. The Executive Officer finds that the adoption of these regulations will not have a significant adverse economic impact on businesses, including the ability of California businesses to compete with businesses in other states.

Small Business Impact

The proposed amended ATCM applies to facilities which operate ethylene oxide sterilizers and aerators, some of which may be defined as small businesses. These facilities are required by the existing ATCM to meet performance-based emission limits based on the best available emission controls. The proposed amendments will not result in any change in emissions of ethylene oxide, but will simplify compliance demonstration and testing for facilities operating reclamation system control equipment. Consequently, the proposed amendments to section 93108 will not result in an increase in the cost to small businesses. The proposed amendments will benefit large commercial facilities by providing one regulation that satisfies both state and federal law, thereby streamlining compliance. Any increase in the cost of compliance to large commercial facilities relative to the cost of complying with the existing ATCM is mandated by the requirements of the NESHAP, and as such will be incurred regardless of any action taken to adopt section 93108.5.

In accordance with Government Code section 11346.54, the Executive Officer has determined that the amended regulatory action will not affect the creation or elimination of jobs within the State of California, the creation of new businesses or the elimination of existing businesses within California, or the expansion of businesses currently doing business within California. A detailed assessment of the economic impacts of the amended regulatory action can be found in the Staff Report.

Prior to adopting the amendments, the Board must determine that no alternative considered by the agency would be more effective in carrying out the purpose for which the regulations are amended or would be as effective and less burdensome to affected public and private persons than the amended action.

Submittal Of Comments

The public may present comments relating to this matter orally or in writing. To be considered by the Board, written submissions must be addressed to and received by the Clerk of the Board, Air Resources Board, P.O. Box 2815, Sacramento, CA 95812, no later than 12:00 noon, May 20, 1998, or received by the Clerk of the Board at the hearing.

The Board requests, but does not require, that 20 copies of any written statement be submitted and that all written statements be filed at least 10 days prior to the hearing. The Board encourages members of the public to bring to the attention of staff in advance of the hearing any suggestions for modification of the amended regulations.

Statutory Authority And Hearing Procedures

Amendments to these regulations are proposed pursuant to the authority granted to the ARB in Health and Safety Code sections 39600, 39601, 39650, 39655, 39656, 39658, 39659, 39665, and 39666. These regulations are proposed to be amended to implement, interpret, and make specific sections 39650, 39655, 39656, 39658, 39659, and 39666 of the Health and Safety Code.

The public hearing will be conducted in accordance with the California Administrative Procedure Act, Title 2, Division 3, Part 1, Chapter 3.5 of the Government Code, commencing with section 11340.

Following the public hearing, the Board may adopt the amended regulations as proposed or with nonsubstantial or grammatical modifications. The Board may also adopt the amended regulations with other modifications if the modifications are sufficiently related to the originally proposed text such that the public would be adequately placed on notice that the regulatory language as modified could result from the proposed regulatory action. In the event that such modifications are made, the full regulatory text, with the modifications clearly indicated, will be made available to the public for written comment at least 15 days before it is adopted. The public may request a copy of the modified regulatory text from the Air Resources Board Public Information Office, 2020 L Street, Sacramento, California, 95814, (916) 322-2990.

CALIFORNIA AIR RESOURCES BOARD

Michael P. Kenny
Executive Officer

Date: